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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/599,904

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Andrew John Easton

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EXAMINER

CALAMITA, HEATHER

ART UNIT

PAPER NUMBER

1637

NOTIFICATION DATE

DELIVERY MODE

02/24/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/599,904	<b>Applicant(s)</b> EASTON ET AL.	
	<b>Examiner</b> HEATHER G. CALAMITA	<b>Art Unit</b> 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 December 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 11-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/15/2007</u> .   | 6) <input type="checkbox"/> Other: _____                          |

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## DETAILED ACTION

### *Election/Restrictions*

1. Applicants' election with traverse of Group 1 claims 1-10 in the reply filed on December 30, 2008, is acknowledged. The traversal is on the ground(s) that no lack of unity was found by the international searching authority. This is not found persuasive because while this is the national stage examination of the application, the examination is being carried out by a different searching authority and different examiner. Each application is examined on its own merits and for the reasons already made of record the instant claims lack unity of invention.

The requirement is still deemed proper and is therefore made **FINAL**.

### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Olivo et al. (Virology, 1998).

With regard to claim 1, Olivo et al. teach an assay method for studying the effect of at least one compound on RNA virus entry, RNA replication, transcription or encapsidation, the method comprising the steps of:

(a) providing an RNA molecule containing (i) at least a portion of the genome of an RNA virus of interest, (ii) a copy of a reporter gene flanked by viral regulatory sequences to direct RNA synthesis by a viral RNA polymerase and (iii) one or more sequences of RNA encoding packaging signals, the RNA molecule being packaged within a virus-like particle (see the abstract and p. 199 col. 2 first paragraph under *BHK cells are susceptible to infection and support*

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*minigenome replication and transcription*, p. 202 col. 2 , where the compounds are ribavirin and neutralizing antibody and p. 200 figure 1 and legend);

(b) incubating a cell containing the RNA molecule with the or each compound, the cell being capable of causing the replication of the RNA molecule (see p. 200 figure 1 and legend and p. 202 col. 2 , where the compounds are ribavirin and neutralizing antibody); and

(c) detecting the presence of any reporter gene product (see p. 199 col. 2 first paragraph under *BHK cells are susceptible to infection and support minigenome replication and transcription* and p. 200 figure 1 and legend).

With regard to claim 2, Olivo et al. teach the RNA virus is a negative strand RNA virus (see the abstract and p. 200 figure 1 and legend, where RSV is a negative strand virus).

With regard to claim 3, Olivo et al. teach the RNA molecule is produced by (i) introducing an RNA molecule encoding (1) at least a portion of the genome of an RNA virus of interest, (2) a copy of a reporter gene flanked by viral regulatory sequences to direct RNA synthesis by the viral RNA polymerase and (3) one or more sequences of RNA encoding packaging signals, into a cell infected with the cognate virus; or (ii) introducing a plasmid capable of directing the synthesis of the RNA molecule into a cell infected with the cognate virus and containing the components required to enable the plasmid to direct synthesis of the RNA; or (iii) introducing a plasmid capable of directing the synthesis of the RNA molecule containing the genes necessary for virus replication and packaging into a cell containing the components required to enable the plasmid to direct synthesis of the RNA and containing the components required for viral replication and transcription (see p. 200 figure 1 and legend).

With regard to claim 4, Olivo et al. teach the RNA molecule defined in step (i) is either negative-sense or positive-sense RNA (see the abstract and p. 200 figure 1 and legend, where RSV is a negative strand virus).

With regard to claim 5, Olivo et al. teach the reporter gene is a heterologous reporter gene (p. 200 figure 1 and legend and p. 199 col. 2 first paragraph under *BHK cells are susceptible to infection and support minigenome replication and transcription*, where the reporter is lacZ or CAT ).

With regard to claim 6, Olivo et al. teach the RNA molecule is incapable of independent replication and the cell in step b contains components necessary for replication and packaging of the RNA molecule (see p. 200 figure 1 and legend and p. 199 col. 2 first paragraph under *BHK cells are susceptible to infection and support minigenome replication and transcription*).

With regard to claim 7, Olivo et al. teach the RNA molecule may or may not lack one or more genes encoded by the native genome of the negative-strand RNA virus (see p. 200 figure 1 and legend and p. 199 col. 2 first paragraph under *BHK cells are susceptible to infection and support minigenome replication and transcription*).

With regard to claim 8, Olivo et al. teach the negative-strand RNA virus is a paramyxovirus (see the abstract where RSV is a paramyxovirus).

With regard to claim 9, Olivo et al. teach the negative-strand RNA virus is human respiratory syncytial virus (RSV), or avian pneumovirus (APV) (see the abstract).

With regard to claim 10, Olivo et al. teach the reporter gene is chloramphenicol acetyltransferase (CAT), luciferase, green fluorescent protein (GFP), 13-galactosidase, or secreted alkaline phosphatase (see p. 199 col. 2 first paragraph under *BHK cells are susceptible to infection and support minigenome replication and transcription*, where the reporter is CAT).

### ***Summary***

3. No claims were allowable.

### ***Correspondence***

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Heather G. Calamita whose telephone number is 571.272.2876 and whose e-mail address is heather.calamita@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route.

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The examiner can normally be reached on Monday through Thursday, 7:00 AM to 5:30 PM.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at 571.272.0782.

Papers related to this application may be faxed to Group 1637 via the PTO Fax Center using the fax number 571.273.8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to 571.272.0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Heather G. Calamita/  
Examiner, Art Unit 1637